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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,720	07/17/2000	Martin Nicklin	MSA-021.01	7893

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EXAMINER

HAMUD, FOZIA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/617,720

Applicant(s)  
Nicklin et al

Examiner  
Fozia Hamud

Art Unit  
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Sep 17, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above, claim(s) 1-11, 13, 22, and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12, 14-21, 24, and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **Detailed Office Action**

1. Receipt of Applicants' arguments and amendments filed in Paper No.14 on 12 September 2002 is acknowledged. Claims 12, 14-21 and 24 have been amended, and claim 25 has been added. Thus claims 12, 14-21 and 24-25 are under consideration. Claims 1-11, 13 and 22-23 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

#### ***Response to Amendment:***

2. The following previous objections and rejections are withdrawn in light of Applicants amendment filed on 12 September 2002 in Paper No.14:

(I) The rejection of claims 17 and 19 made under 35 U.S.C.§112, first paragraph, for not providing deposit information.

(II) The rejection of 14 and 19 made under U.S.C. § 112, second for not reciting hybridization conditions.

(III) The rejection of claims 12, 14-16, 18-19, 20-21 and 24 are rejected under 35 U.S.C § 102(b) as being anticipated by Ford et al (U.S Patent 6,294,655).

#### ***Specification***

3a. The disclosure stands objected to, for not providing the actual Accession Number and the date in which the deposit was actually made for the deposited material. Applicants submit that they are in the process of facilitating the deposit of the hIL-IL1 clone with ATCC and upon receipt of an

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Accession Number and deposit date will amend the specification accordingly. This objection will be withdrawn, after said amendment to the specification is filed.

***Claim objections:***

4a. Claims 18 and 19 stand objected to, because these claims recite Accession Numbers for EST sequences. Applicants submit that they are in the process of preparing an amended sequence listing so that said sequences are referred to by a sequence identifier instead of an Accession Number. Once this amendment is filed, the objection to claims 18 and 19 will be withdrawn.

***Claim rejections-35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 12, 18, 20, 21 and 24 stand rejected under 35 U.S.C. 112, first paragraph for reasons of record set forth in the office action mailed on 12 March 2002, in Paper NO:13, pages 5-7.

Applicants argue that the amendment to claims 12, 18, 20 and 21 (which recite 70-90%) to include the structural limitation "hybridizes under stringent conditions" to a referenced DNA sequence should be sufficient to overcome the scope rejection made under 35 U.S.C. 112, first paragraph.

This argument is not found persuasive, because Applicants have only disclosed an isolated nucleic acid comprising SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3. Claim 12 recites "an isolated nucleic acid which comprises at least 70% of SEQ ID NO:1 or complement thereof, wherein said isolated nucleic acid hybridizes ...to SEQ ID NO:1" however, the specification does not

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disclose an isolated nucleic acid sequence having at least 70% identity to SEQ ID NO:1 which also hybridizes to SEQ ID NO:1. claim 20 is drawn to an isolated nucleic acid which is at least 75% to SEQ ID NO:2 and claim 21 is drawn to an isolated nucleic acid that is at least 95% of SEQ ID NO:3. The specification does not provide the requisite examples nor a representative number of different sequences that would allow the skilled artisan to produce a polynucleotide having at least 70%, 75% or 95% sequence identity to SEQ ID Nos:1, 2 or 3 respectively, that would retain the desired function of the native sequence, nor does the disclosure provide criteria that explicitly enable such critical features. There is no guidance in the specification as to how one of ordinary skill in the art would generate a polynucleotide or a polypeptide encoded thereby, other than that exemplified. The issue here is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record.

Therefore, Applicants are not enabled for an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:1, SEQ ID NO:2 and SEQ ID NO:3. Applicants do not teach a nucleic acid that shares 70% identity to SEQ ID NO:1 and encodes the desired protein. Instant specification describes SEQ ID NO:2 and 3 as being two alternate 5' ends of human IL-IL1 gene, (see page 4). SEQ ID NO:2 comprises 39 and SEQ ID NO:3 comprises 2-42 nucleotide, and instant specification does not teach which 25% and which 5% of SEQ ID Nos:2 and 3, respectively could be altered while still identifying the two SEQ ID NOs as 5' alternate ends of the of the human IL-IL1. To practice the instant invention in a manner consistent with the breadth of the claims would not require just a repetition of the work that is described in the instant application but a substantial

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inventive contribution on the part of a practitioner which would involve the determination of those nucleotide sequences of the disclosed naturally-occurring nucleic acid, which are required for functional and structural integrity of the claimed nucleic acid. It is this additional characterization of the disclosed nucleic acid that is required in order to obtain the functional and structural data needed to permit one to produce a nucleic acid which meets both the structural and functional requirements of the instant claim that constitutes undue experimentation. (For more details, see the the office action mailed on 12 March 2002, in Paper NO:13, pages 5-7).

5b. The rejection of claims 12, 18, 20, 21 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for reasons of record set forth in the office action mailed on 12 March 2002, in Paper NO:13, pages 7-9.

Applicants argue that the amendment to claims 12, 18, 20 and 21 (which recite 70-90%) to include the structural limitation "hybridizes under stringent conditions" to a referenced DNA sequence should be sufficient to overcome the scope rejection made under 35 U.S.C. 112, first paragraph.

However, this argument is not found persuasive, because Applicants provide written description only for the nucleic acid of nucleotide sequence set forth in SEQ ID NO:1, 2 and 3, and therefore the written description is not commensurate in scope with claims 1, 20 and 21 which is drawn a nucleic acid comprising a sequence having at least 70%, 75% and 95% to SEQ ID Nos:1, 2 and 3 respectively.

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With the exception of SEQ ID NO: NOs:1, 2 and 3 the skilled artisan cannot envision the detailed structure of the encompassed polypeptide or the polynucleotide encoding such and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Therefore, it does not appear that the inventors were in possession of a a nucleic acid comprising at least 70% of SEQ ID NO:1, 75% of SEQ ID NO:2 or 95% of SEQ ID NO:3.

***Claim rejections-35 U.S.C. § 112, second paragraph***

6. Claims 12, 14-17, 19, 20, 21, 24 and 25 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6a. Claims 12, 14, 19, 20 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: these claims recite hybridization conditions, however, the claims do not recite the temperature of the wash conditions. Therefore, it is unclear whether the recited temperature is for both hybridizing and washing conditions. Appropriate correction is required.

Claims 15-16 are rejected under 35 U.S.C. 112, second paragraph, in so far as they depend on claim 14 for the limitations set forth directly above.

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6b. Claim 25 recites "an isolated nucleic acid encoding a polypeptide of SEQ ID NO:10", however, SEQ ID NO:10 in the instant case is a nucleotide sequence and not an amino acid sequence. Appropriate correction is required.

***Conclusion***

7. No claim is allowed.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
24 February 2003

*Gary L. Kunz*  
GARY L. KUNZ  
SUPERVISOR  
FEB 24 2003